K060289

## 510(k) Summary

**(1) Submitter's Name / Contact Person:** Frontline Medical,
Innovation Works,
National Technology Park,
Castletroy,
Limerick,
Ireland

JUL - 7 2006

Contact Person: Paul Slattery,
Chief Technical Officer
Tel: (011) 35387 4184183

**(2) Device Name:**

Trade Name: EpiStat Vaginal Tamponade Balloon
V-Stat Vaginal Tamponade Balloon

Common Name: Vaginal Packing

Classification Name: Obstetric-Gynecological general manual instrument

Device Classification: Class I, 21 CFR §884.4520

**(3) Identification of Predicate Devices:**

| # | Manufacturer | Device | 510(k) No. |
|---|---|---|---|
| 1 | National Hospital Packaging | Vag Packing | None (Class I) |
| 2 | Cook OB/GYN | Tamponade Uterine Balloon Catheter Set | K013597 |
| 3 | Boston Medical Products | Epi-Stop Epistaxis Catheter | K972077 |

**(4) Description of the Device:**
EpiStat is an inflatable balloon tamponade device designed to provide a safe and effective method of temporarily tamponading the vagina to assist with post partum episiotomy repair. EpiStat is provided sterile in peel-open packages and intended for one-time use.

V-Stat is an inflatable balloon tamponade device designed to provide a safe and effective method of achieving haemostatic control by direct or indirect compression of vaginal tissues as a result of the inflation of a balloon using air. V-Stat is provided sterile in peel-open packages and intended for one-time use.

**(5) Statement of Intended Use:**

EpiStat is intended for use by physicians and trained obstetrics/gynecology nurse practitioners during episiotomy repair procedures. EpiStat is intended to temporarily tamponade the post partum discharge of fluids from the vagina in order to assist with the episiotomy repair procedure.

V-Stat is intended for use by physicians for temporary haemostatic control following vaginal surgery procedures such as (a) post operative packing for posterior and anterior vaginal repairs (b) brisk introperative bleeding during urethral sling procedures and post operative packing to control sub-pubic haematoma following urethral sling procedures.

**(6) Predicate Device Comparison:**

EpiStat and V-Stat are substantially equivalent to the National Hospital Packaging, Vag Packing (listed on December 16, 1992) in terms of its indications for use and functional effectiveness. EpiStat and V-Stat incorporate the same general design, materials and principles of operation used in other inflatable balloon tamponade devices. The EpiStat and V-Stat are substantially equivalent to the Cook OB/Gyn, SOS Bakri Balloon Tamponade (K013597 cleared for marketing by the Center on April 17, 2002) in terms of its physical construction and principle of operation and employs the same deployment methology and method of operation (inflated using air) as the Boston Medical Products Epi-Stop Epistaxis Catheter (K972077 cleared for marketing on June 26, 1997). The device will be manufactured according to specified process controls and in compliance with an ISO 9001/ISO 13485 Quality Assurance Program. The device will undergo packaging and sterilization procedures in compliance with internationally recognized standards. Being similar with respect to indications for use, materials and physical construction to predicate devices, the device meets the requirements for section 510(k) substantial equivalence.

**(7) Performance Testing:**

Performance testing involving balloon burst strength, tensile strength, leak testing, packaging qualification, sterilization validation and biocompatibility testing in compliance with ISO 10993-1 has been successfully completed. The successful tests demonstrated the EpiStat/V-Stat device consistently performed within its design parameters, is safe and effective and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 7 2006

Mr. Paul Slattery
Chief Technical Officer
Frontline Medical, Innovation Works
National Technology Park
Limerick
IRELAND

Re: K060289
Trade/Device Name: V-Stat™ Vaginal Tamponade Ballon and Epistat™ Vaginal Tamponade Ballon
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: KNA
Dated: June 23, 2006
Received: June 26, 2006

Dear Mr. Slattery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

**510(k) Number (if known):** K060289

**Device Name: Epistat Vaginal Tamponade Balloon**

**Indications for Use:** EpiStat is intended for use by physicians and trained obstetrics/gynecology nurse practitioners during episiotomy repair procedures. EpiStat is intended to temporarily tamponade the post partum discharge of fluids from the vagina in order to assist with the episiotomy repair procedure.

Prescription Use ___X___ AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANTOHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060289

## Indications for Use

**510 (k) Number (if known): K060289**

**Device Name: V-Stat Vaginal Tamponade Balloon**

**Indications for Use:** Indications for Use: V-Stat is intended for use by physicians for temporary haemostatic control following vaginal surgery procedures such as (a) post operative packing for posterior and anterior vaginal repairs (b) brisk intraoperative bleeding during urethral sling procedures and post operative packing to control sub-pubic haematoma following urethral sling procedures.

Prescription Use _X_ ~~AND~~/OR Over the Counter Use____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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